Cardima REVELATION® Tx Microcatheter Ablation System

Device Design

The Cardima® Inc., REVELATION® Tx Microcatheter with NavAblator RF Ablation System is intended for the treatment of atrial fibrillation (AF) in patients with drug refractory paroxysmal AF by mapping, pacing, and ablating in the right atrium.

The design of the REVELATION Tx is based on angioplasty guidewire technology and uses small, coiled electrodes that are highly flexible and conform to the anatomy of the atrium to deliver RF energy at a higher density than conventional ("hot tip") RF ablation catheters (including the NavAblator). This technology produces lesions that are equivalent in depth to those created with a conventional RF ablation catheter but are thinner and require less RF energy to create them.

Study Design

The safety and effectiveness of this system for the stated intended use has been investigated over a three-phase (IIa, IIb and III) prospective, multi-center clinical trial with the patient serving as his own control. The study population included patients with no significant structural heart disease and drug refractory, paroxysmal AF, with a documented episode frequency of at least 3 symptomatic episodes per month as documented by event monitoring devices over 30 days.

The primary endpoints for this study were evaluated at six months post treatment in >80 patients. The primary endpoints were (1) reduction of 50% in frequency of spontaneous symptomatic AF episodes (75% reduction in patients with = 4 episodes/month) and (2) the incidence of major adverse events. The secondary clinical endpoint was quality of life based on two recognized instruments, general health measured by the SF-36 and symptoms and severity of AF measured by the Atrial Fibrillation Severity Scale (AFSS). Clinical (patient) success was defined as a reduction in frequency of symptomatic episodes compared to baseline while maintained on the same anti-arrhythmic drug regimen or reduced dosage.

Results

Two hundred seventeen (217) patients were screened, 120 treated, and 6-month follow up data have been compiled for 81 patients showing an overall success rate of 85.2% (69/81) in meeting the primary endpoint of a reduction in frequency of symptomatic AF episodes of at least 50% after 6 months. In addition, 54.3% (44/81) of these subjects reported a 100% reduction in episodes at 6 months. The rate of major complications was 3.4% and included a pericardial effusion, a sinus node injury, a stroke, and an AV fistula. Other adverse effects were largely consistent with cardiac catheterization procedures, including skin burns, sore throat, back pain, etc. Minor complications numbered 53 for 31 subjects (27%).

Patient Success was demonstrated for at least 60% (50/81) of the subjects who had both a decrease in episode frequency and either maintained the same anti-arrhythmic drug regimen or experienced a decrease in dosage.

These results were accompanied by significant improvements in quality of life for study subjects who reported improvements in all categories of quality of life and statistically significant ($p<0.05$, paired t-test) improvements for six of the eight mean scores of the SF-36. Subjects also reported overall improvement of approximately 25% ($p<0.0001$) and highly statistically significant improvements in episode frequency and reduced episode duration ($p<0.0001$ and $p<0.001$, respectively) according to the AFSS scores.

Conclusion

These results indicate acceptable effectiveness and safety and offer the benefit of a less invasive approach to treating AF